

Subject's/LAR Name:
Title of Research Protocol: Statin Therapy in Acute Influenza
Principal Investigator's Name: Maureen Chase MD MPH
Protocol #: 2013P-000026

Verbal Consent – Rapid Antigen Test (RAT)

Hello, my name is _____ and I am a researcher at the Beth Israel Deaconess Medical Center (BIDMC) working with Dr. Maureen Chase who is the study doctor and may be contacted with any questions. We are asking for your permission to test you for the flu in order to determine if you will be eligible for a new research study about the new use for statins to help treat people with the flu.

The purpose of this test, called a Rapid Antigen Test (RAT) is to find out if you have influenza (flu) virus present in your nose. There are two (2) types of flu, A and B, and the RAT can test for both of these types. This test for flu has been approved for use and is not an experimental procedure.

If the results of this test are positive for the flu, we will discuss the medication trial with you in much more detail and ask you to sign a separate consent.

The procedure will take about 1 minute and results will be available in 15 minutes. A research staff member will insert a swab into the back of your nose and swish it around to collect nasal secretions to test for the presence of the flu virus. The swab sample will be used to find out if you have either form of the flu (A or B). All that is required of you is to sit still while the samples are being collected. The samples collected for the flu test and the test kits will be safely thrown away once the final results have been obtained and recorded.

The side effects of the RAT swab collection are generally mild. They include sneezing, runny nose, watery eyes and soreness where the nose is swabbed.

Your participation is completely voluntary, and choosing not to participate would not affect your care. You may stop taking part in this study at any time. Your decision to withdraw from the study will not directly affect your medical care at BIDMC.

You will not receive any direct benefit from your participation. You will not be charged for the RAT test nor will you receive payment for participating. I will give you a study information sheet to take home with you.

If you have any questions before, during or after your participation in the study, you may ask me directly or contact Dr. Maureen Chase by phone (617-754-2341). You may also contact the Human Subjects Protections Office at 617-667-0469 if you have questions about your rights as a study participant.

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Would you be willing to allow us to test you for the flu?

Yes _____ No _____

VERBAL CONSENT OBTAINED from _____

by _____
Print Name

Signature **DATE**

Patient Information Sheet

Statin Therapy in Acute Influenza

Principal Investigator: Maureen Chase MD MPH

Why is this test being done?

In order to determine if you are eligible for a research study about the new use for statins to help treat people with the flu, we need to test you for the flu.

You have been asked to take this test *because* you have had flu-like symptoms such as fever, cough and headache. The purpose of this test, called a Rapid Antigen Test (RAT) is to find out if you have influenza (flu) virus present in your nose. There are two (2) types of flu, A and B, and the RAT can test for both of these types. This test for flu has been approved for use and is not an experimental procedure.

If the results of this test are positive for the flu, we will discuss the medication trial with you in much more detail and ask you to sign a separate consent.

Your participation is completely voluntary and choosing not to take the flu test will not affect your medical care at BIDMC.

You will not receive any direct benefit from your participation. You will not be charged for the RAT test nor will you receive payment for participating.

How long will the procedure last? The procedure will take about 1 minute and results will be available in 15 minutes.

What will happen? A research staff member will insert a swab into the back of your nose and swish it around to collect nasal secretions to test for the presence of the flu virus. The swab sample will be used to find out if you have either form of the flu (A or B). All that is required of you is to sit still while the samples are being collected. The samples collected for the flu test and the test kits will be safely thrown away once the final results have been obtained and recorded.

What are the risks from being in this research study? The side effects of the RAT swab collection are generally mild. They include sneezing, runny nose, watery eyes and soreness where the nose is swabbed.

What are the possible benefits from being in this research study? You will not receive any benefits from participating. .

Will I be paid to participate? You will not be paid to participate. You will not be charged for the RAT test nor will you receive payment for participating. I will give you a study information sheet to take home with you.

Who can I speak with if I have questions about this research study? Maureen Chase MD is the person in charge of this research study. You can call her at 617-

754-2323 or email her with questions at mchase1@bidmc.harvard.org. If you have any questions about your rights as a research participant, please contact the Human Subjects Protections Office at 617-667-0469.